Date:07/07/07
Response to Office Action dated 04/04/07
Re: 10/634,369

Thank you for helping me straighten out some mistakes. It also made me realize I have not communicated what my invention really is. I have included some comments from users of my cannulas to help convey that this invention is a big deal with many improvements that make a difference in their lives. I also took some photos of brand X and my cannulas to show the difference. My invention is simple and very effective and the pieces have been around a long time but no one else has ever put the pieces together. If they had it would be too valuable not to have it patented. In a nutshell I will show that using soft (actually more flexible) tubing is contrary to what is known about making cannulas. And I will show that using more flexible tube for a cannula is a worthless idea without a second bit of information about the nosepiece. There isn't anything to suggest softer hose let alone anything that suggests both the more flexible hose and a certain nosepiece.

Therefore, before I address each point in the letter, I want to attempt to clarify what my invention is. It is an invention in its truest sense. It is very effective and, although the end result is simple, it required, insight, craftsmanship, perseverance and a bit of luck. This invention must be considered as a whole because the individual pieces aren't very new (except the nosepiece). Simple does not automatically mean obvious, particularly when it is completely opposite to what has been known for many years

Patent and design history of the nasal cannula

Vinyls (PVC or polyvinylchloride) were first employed to fabricate disposable medical devices during World War II. Since then, vinyl has become by far the most commonly used polymer in the medical plastics industry.

Today, millions of cannulas are manufactured per year and nearly all of them use a design that dates back to 1957. In the 50 years since there have been two more major innovations (out of at least 85 patents and applications related to cannulas) and mine is the fourth. Short story:

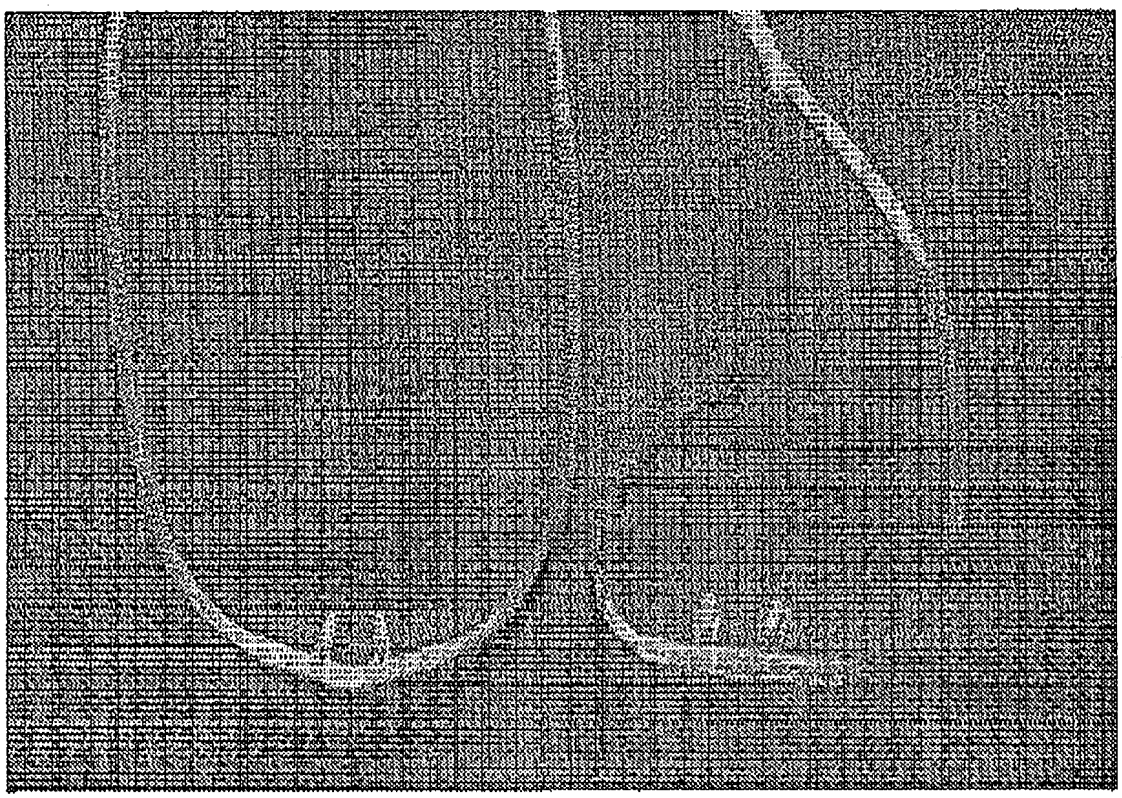
1. 1957, #2,931,358, D.S. Sheridan-used two small diameter oxygen tubes instead of straps to support nosepiece. Actually the ends of the tubes were pointed into the nostrils
2. 1969, #3,643,660, Hudson-invented an injection-molded nosepiece designed to align itself with the face to point the prongs so they don't blow oxygen on the sensitive nasal wall. Inexpensive to produce, these cannulas were manufactured in the hundreds of millions and are still the most widely used. The cannula with an injection molded nosepiece supported by two hoses is what I refer to when I say "modern cannula".
3. 1977, #4,106,505, Salter-introduces a dip molded nosepiece that is softer and points the oxygen prongs more accurately. The body is tall and narrow and wraps

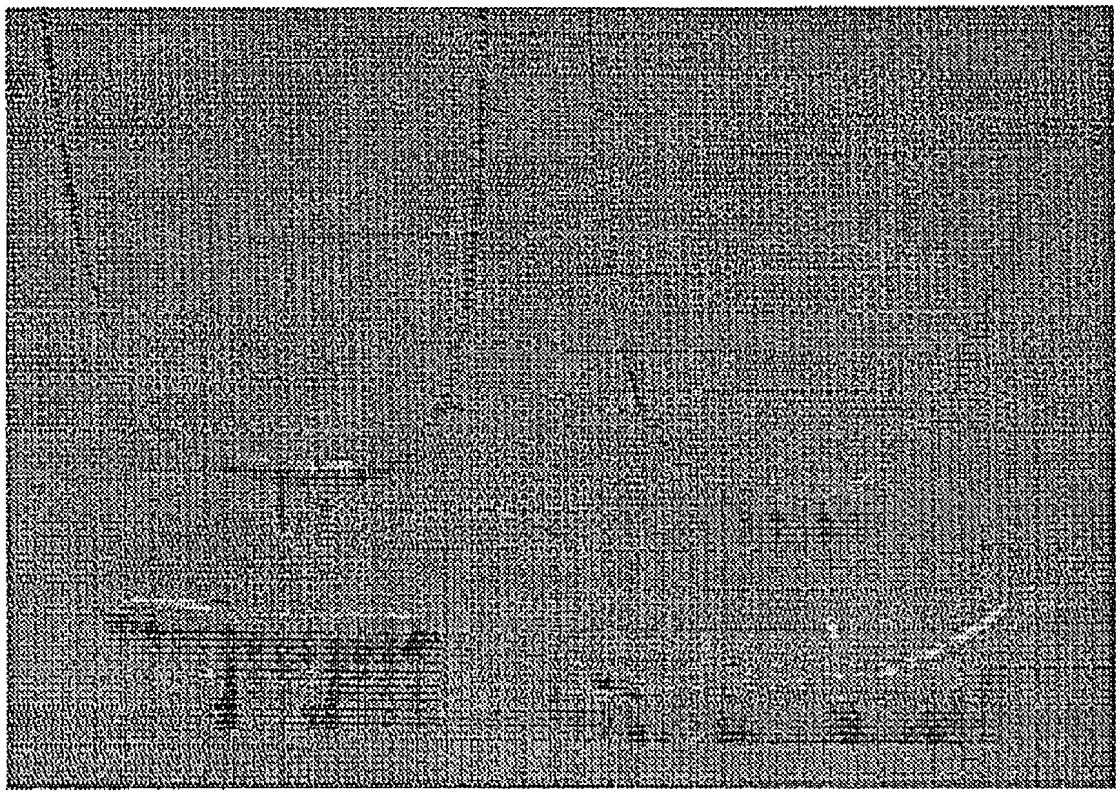
around the upper lip like a belt. The prongs point in the tall direction so when the belt is on the lip the prongs point up. Now that the patent has run out there are plenty of imitators using dip-molding, which are considered premium cannulas. Since then, nothing new has reached the marketplace.

All three of these inventions and all known cannulas on the market today use the same tubing. It is the same material, the same hardness and the same dimensions because time has shown that is what works best for cannulas. In order for the cannula to work properly, the tubing has to be stiff in the twisting direction so that holding one end rigid will make it hard for the nosepiece at the other end to rotate, thus keeping the oxygen delivery prongs pointing upward when gravity wants them to point down. This is not widely known within the industry and various other reasons for using stiff tubing are often given, usually related to crush resistance. The idea to use soft tubing to improve comfort is a reasonably obvious idea to a person outside the industry but those within know that it doesn't work as expected because, even though the tubing is more comfortable, the cannula pointing is uncontrolled and that outweighs any improvements. Therefore, the Holy Grail of cannula design is to figure out how to use more flexible tubing without the downside and still keep the simplicity of the "tubing supported nosepiece" design of a modern cannula. I have included some photographs to better illustrate prior art and my own invention.

Pictures

Below is a picture of my cannula (left) with extra flexible tubing and a standard cannula (right) with normal stiff tubing that refuses to straighten out. In both cases the prongs point upwards correctly but they do so for completely different reasons. Another picture shows what happens when the nosepiece on the right is used with the flimsy tubing on the left. Stiff tubing (right) is harder to twist and this keeps the prongs from rolling over. Notice the nosepiece on the left has most of its weight below where the tubing attaches. This makes it bottom heavy and the prongs point up. It is clear from the picture that the tubing on the left is better behaved than the tubing on the right.





In the picture above, both nosepieces are held by very flexible tubing. The left side shows what happens when flimsier tubing is substituted with a regular nosepiece. It turns right over due to gravity because the tubing is so easy to twist it offers no resistance. That is why nobody has used this kind of tubing for cannulas. The idea to soften the tubing seems obvious but in practice it causes other problems that outweigh any benefit.

I put a bend in each arm of the right hand nosepiece to raise the point where the tubing attaches. Now the weight of the horizontal body will cause the nosepiece to pivot about the tubing attachment points until it is at the bottom and the prongs are at the top. Now the nosepiece does not rely on the rigidity of the tubing to maintain its upright orientation so the designer is free to use tubing that bends easily when the head is turned. As the picture shows, the change to the nosepiece is relatively minor and does not improve the cannula very much by itself but when used with flexible tubing the improvement in comfort was much more than expected. My curiosity about why this was so led me to discover the link between nosepiece center of gravity and tubing stiffness.

My invention

I am seeking a patent to protect my idea of combining very flexible tubing with a nosepiece that can remain upright without relying on the stiffness of tubing. A variety of nosepiece shapes will work in this application and it is not my intent to try to patent them all. There is at least one cannula currently sold that uses a nosepiece suited for use with flexible tubing. This would markedly improve the comfort of the cannula but the manufacturer does not know that this possibility exists. They have all learned that soft

tubing does not work for cannulas. The fact that no manufacturer has made this significant improvement is fairly proof that none of them have the information I am willing to disclose. The tubing and the correct nosepieces have been around for at least ten years, however the idea to combine the two is contrary to common wisdom and a person skilled in the arts would have no expectation of success in doing so. My invention, then, is any cannula that uses my idea to increase comfort.

I invented a new nosepiece to solve additional problems with cannulas that are not fixed by the tubing. It locates itself accurately and solidly and this gives the cannula unmatched ability to consistently keep the delivery prongs pointed down the middle and not against the walls. This continues to be a problem with current cannulas and many users suffer internal sores or a bloody nose. People report that their sores heal in two days after using my cannulas.

Although not required to make this invention work, a cannula that uses this nosepiece along with the preferred tubing has almost none of the problems associated with modern cannulas. The difference in comfort is astounding and thousands of users agree. Later I have included customer comments to illustrate this point.

The last part of my invention concerns the main supply tubing. It turns out the same wonderful material can be used to make the larger tubing that connects to an oxygen source. Its flexibility makes it behave much better than regular tubing and unexpectedly eliminated a common problem with regular tubing as I will explain later

This understanding came to me after I made the cannula and is a new and fundamental discovery. This information is not known in the industry, not seen in published literature, trade journals or books nor was it alluded to in 85 cannula patents I read.

Why is my cannula so comfortable compared to regular ones?

The combination of my nosepiece design and extreme tubing flexibility make a cannula that is vastly more comfortable than any other. Later I have included comments from users of my cannulas and some of the reasons for comfort were surprising to learn.

The tubing I use is made from ultra-high molecular weight (UHMW) PVC and this gives the tubing extreme flexibility that can't be obtained with regular PVC and it is this flexibility that makes my cannula work as well as it does. Regular PVC tubing can be made fairly soft but it still isn't very flexible and, conversely, the UHMW tubing can be just as hard as currently used tubing and still work well because of its great flexibility. A high molecular weight doesn't mean the tubing is heavier, it just means that the chains of molecules are longer. UHMW PVC can be made very soft and rubbery and was intended to be a viable replacement for expensive silicone tubing.

Ordinary PVC has "memory" that causes a lot of the problems associated with cannulas. The tubing will adopt a shape over time and is slow to relax when forced into another shape. An example is the coil shape of a packaged cannula that is slow to go away when

it is removed. It will adopt a shape on the user's head that is reluctant to change when the head is moved. Pulling the tubing tight against the skin forces the tubing to follow movements. Of course the tightness causes another set of problems. My tubing has very little memory and that, combined with rubbery qualities make it work so well. Silicone also possesses those qualities and would work well in this application. Unfortunately it is difficult to bond and is very expensive.

Compared to regular PVC, my tubing feels like silk and drapes over things nicely. You can move a section of tubing and right next to it the tubing stays put. As part of a cannula it will bend freely when a person turns their head and nothing else is disturbed. With regular tubing, such a head movement will try to bend the stiff tubing and the whole length of tube is affected, usually causing the nosepiece to move. To prevent movement the tubing must be pulled tight and this tightness causes a multitude of discomforts that are the subject of a great number of patents. I have included a number of patent drawings to show the many devices intended to address these issues. **My cannula does not need to be tight and this alone eliminates every single problem associated with tightness.** The tubing I use remains flexible in cold weather where regular PVC has been known to snap in two. Even without snapping, regular PVC is so stiff it is difficult to wear. One of the intended uses of the UHMW material was in shoe soles that must remain flexible when cold.

The nosepiece solves virtually every remaining problem. The biggest of these is the tendency for cannulas to point the oxygen against the nasal walls causing a bloody nose or sores. Another is the tendency to rock from side to side under the nose; sometimes so much that one of the prongs comes out and wastes oxygen.

The vee-shaped arms of my nosepiece fit the face and touch the skin on both sides so it has no tendency to rock from side to side. The straight central section used in all other cannulas acts like a see-saw that pivots on the bridge between the nostrils. The prongs of my nosepiece are molded at a fixed angle relative to the vee-body so when the body is nestled in place the prongs are pointed down the middle of the nostrils. In fact, it is difficult to position the nosepiece so oxygen blows against the walls. My cannula is the only medical treatment available to stop bloody noses. Currently ointments and gauze are the only other options.

My nosepiece also has prongs that are extremely flexible at the ends so they don't disturb nasal hairs. I learned that once you get below a certain thickness at the tips, the sensation of something in the nose disappears since nasal hairs aren't disturbed by the thin edge. The prongs taper to Saran Wrap-like thickness at the very tips. This turns out to be very difficult to do with the dip molding process often used to make the most comfortable cannulas. I consulted with many experts in the process and ended up developing my own tooling and method. The nosepiece also uses prongs that curve inward towards the tips. This helps avoid the inward sloping walls of the nasal passages.

A major part of the cannula is a length of tubing, somewhat larger in diameter to the nosepiece tubing that begins where the two smaller tubes are joined with a two-into-one

part called a fork connector and ends with an end connector that attaches to a source of oxygen. This bigger tubing is usually the same material as the smaller ones so it has the same stiffness problems, particularly in cold weather where the material becomes so rigid that the tubing snaps in two pieces. When this piece of tubing is made from the preferred material it drapes nicely across furniture or objects, bends in a small area without disturbing the rest and lies totally flat on the floor so you feet can't get hooked underneath and is, generally much better behaved. Many times this tubing is up to fifty feet long so a trail of tubing follows the user around. As the person walks around the tubing lifts off the floor or lays back down like a silk string and tubing just inches away doesn't move a bit. That same person using regular tubing will drag long sections of the relatively stiff tubing as they move around the house and there is a much greater chance of getting the tubing caught or dragging across something sharp or hot or can get damaged or spilled. Regular tubing never really flattens out so there are plenty of places where feet can trip on it.

One major benefit of the preferred tubing is that it does not readily twist up like a phone cord. Long sections of regular PVC tubing sometimes have one or several spots where the tubing forms into a twisted loop like the individual threads of carpet. This happens to relieve torsional stress built up as a person turns around or drags it across the floor. Besides the nuisance of having the loops under foot, they often kink at the ends where the tubing reverses direction and the oxygen is restricted or completely blocked. Tubing is often molded with ribs on the inside to keep it from flattening when someone steps on it but these ribs make the problem worse when blockage is caused by kinking instead of crushing. Once a spot in the tubing is kinked the first time it will tend to kink more easily the next time.

When all the preferred elements are combined into one cannula, nearly every major problem is either eliminated or reduced in severity. It is hard to believe it could be so much more comfortable than anything else yet it looks almost the same. This is a perfect example of something where the whole is greater than the sum of the parts. Each portion of the cannula can be used by itself and make an improved cannula but when they are all used together the benefits of one part make the next part work even better and so on. One simple example of this is that very flexible tubing does not try to bend the nosepiece when it is rolled up in a package. Normal tubing acts like a coil spring and the nosepiece has to be thick enough to avoid bending under the force. My nosepiece also has to be thick enough if it is used with regular tubing but it can be thinner and lighter than usual in combination with preferred tubing. So the nosepiece is able to be better due to the flexibility of the tubing and the tubing acts better because there is less weight hanging from it. It is difficult to convey how such relatively minor changes to a cannula could possibly make so large of an improvement so I can let users help me.

I have included several customer comments (found on my website at www.softhose.com) to give an idea of the difference between mine and regular cannulas.

I was so shocked and happy at the difference they make! I can't even begin to tell you the relief I felt, instantly! Thank you so much for making these...

The only thing that has gone right about oxygen for me, so far, had been your cannula. It is so soft, so forgiving, that I truly don't know if it's in place (took a few nighttime wakeups to determine!). Each night when I put it on, I think of my mother and how much she would have liked something so tender on her fragile skin during the last years of her life.

All I can say is WOW! And of course...thank you for developing this wonderful hose! I no longer have 'face dents' or behind the ear irritation and most importantly....the nose piece is SO comfortable! The cannula is so light weight that I hardly know I have one on my face! The hose I purchased from you lays on the floor and I no longer have all that tangled mess in the house and if I happen to step outside for a moment...the hose does NOT get rock hard when it is cold. Thank you! I am off to order more!

I received your cannula and can say without qualification that it is the BEST! It is super comfortable and, most important of all, it stays put. I have been on oxygen 24/7 for 6 years and have tried them all--there's no comparison. I hope you're gearing up for mass production, because when the growing world of oxygen patients find out about it they will demand it from their oxygen providers, just as they did when Helios was invented. I hope you get your patent quick and corner the market.

I did notice that the softhose cannula has the feel of a rubber band, and as such tends to stay in my nose better than the salter labs cannulas. I have always had a problem of the cannula falling out of my nose when sleeping, and would wake up with air being blown into my eyes (or my neck). Your cannula tends to stay in my nose while sleeping. This is a MAJOR bonus!

These people are not engineers and may not know the underlying physics but they know what they feel. The comments cover the cold weather flexibility, disappearance of feeling in the nose due to the very thin tips, the face hugging shape of the nosepiece that keeps it in place, the elimination of cheek grooves and sores because of low tubing tension, the rubber-like qualities that give it such flexibility and its worth as extension tubing that lays flat and resists tangling. These few examples touch on many aspects of the invention that are detailed in the application and they also provide insight as to the real world benefits that stem from certain claimed tubing properties that were rejected in the Office Action.

What am I not trying to patent?

1. I am not asking to patent the idea of using softer tubing to make a cannula more comfortable. In fact, it turns out to be a bad idea and is why nobody "thought" of it before. It may explain why the idea never made it all the way to a patent
2. I did not invent the tubing I use. I am the first to use it in a cannula and am the first to discover some unforeseeable and unexpected advantages.
3. The nosepiece I invented is not the only one that works with flexible tubing. In fact, a few pages earlier, I showed a nosepiece with bent arms that is a first of its kind that has what it takes to use flexible tubing and, indeed, would be better than the best on the market. It took me all of ten minutes to conceive and make the part. A person skilled in the art could read my patent, grasp the underlying

principles and conjure up several designs that would work. I can't patent every possible design.

I am seeking patent protection for the use of very pliable tubing in cannulas that have any nosepiece that will allow it. This is an idea that is contrary to common wisdom, it is not likely that one skilled in the industry would expect success using this type of tubing and it has escaped the minds of thousands of engineers and inventors for the past fifty years. I am also seeking protection for the use of my tubing, or tubing with similar properties, for use as extension tubing or the larger diameter main tubing that connects to the oxygen source. I found that this type of tubing does not form into knots as readily as standard PVC. This was not foreseen by any means and I still can't be certain my understanding is correct. Nonetheless, it does work well.

I am also seeking protection for the design of my nosepiece. It is not the only design that will work with my tubing but it is better than any other on the market. The nosepiece came before the tubing so the first cannulas I made used the vee-shaped nosepiece with regular tubing. These were markedly more comfortable than others so I wish to claim the nosepiece with or without the special tubing.

Points listed in the Office Action

Claim 1-3 rejection- Salter patent describes arcuate angle

As a first-time patent applicant I modified the language in Salter's patent to suit my own device. The Salter cannula (nosepiece) is straight in the middle with arms on both sides that bend at an angle. The words in the patent are "The main body portion has a horizontal axis extending along its length with an elbow formed at each end". This was a major advance in cannulas and is one of the reasons the Salter cannula is widely used. However, it is important to note that it has a straight central section that is wider than the spacing between the prongs. My cannula has no straight central section. It looks like a vee and the shape is critical in that it puts much of the weight below the point where tubing joins the arms. The center of the vee is also a low point that clears the underside of the nose. This is not an incidental point; it is a fundamental reason for the success of this invention. The words are almost identical but differ in this aspect.

Claim 2 rejection-Salter figures show tip with tapering wall thickness
The Salter patent clearly shows the material tapering to a sharp point. This a bit of artistic license as the parts made by Salter are rather blunt at the end. In practice, molding parts with a sufficiently thick body and tips as thin as described in my application is extremely difficult to do. Much time was spent experimenting with mold materials and process variables to be able to mold a part with tips as thin as Saran Wrap. It is not difficult to make thin sections with dip molding (condoms, rubber gloves) but it is very difficult to quickly taper from thick to very thin. The method I developed is an invention on its own. I did all this because I found that below a certain thickness the feeling of something in the nose goes away. It has to be pretty thin, much thinner than any other cannula. Neither the Salter patent, nor any other cannula patent describes the

thickness of the tips in detail. The idea that feeling goes away below a certain thickness is not mentioned in journals, patents or in any products in the marketplace. It makes it much more comfortable and costs no more to produce so it would certainly be included in a patent if someone was aware of it. According to MPEP 2125, the drawings must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art. There is nothing in the drawing that would suggest that feeling goes away below a certain thickness. Making a nosepiece like the one depicted would not have the characteristics claimed in my application. It also says when the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value.

Claim 3 rejection-figure in Salter patent depicts inward curving prongs

Again this is artistic license. The cannulas Salter manufactures, nor any other brand, curve inward because it is less amenable to automated production. My application describes in detail why the curvature is important and provides dimensions. No patent makes any reference to the importance of the curve and nobody manufactures a cannula with this feature so it can be said that the importance is not understood by those skilled in the art. Also there is no indication the drawings are to scale.

Obviousness rejections

Claims were rejected because a person skilled in the art would have been able to come up with an invention like mine based on information published in patents and knowledge of the industry. I will talk of the large numbers of patents that deal with the very problems mine solves but it a more complex manner and with lesser success. I will also show that common knowledge teaches away from the use of very flexible tubing and a skilled person would not expect success. I have more supporting information later.

Claims 4 and 10-10% tensile modulus of tubing

The rejection suggests one skilled in the art would know enough to choose flexible material to prevent damage in the nasalabial area. Claims 4 and 10 concern material for the tubing for which the 10% modulus is a measure of the "rubbery feel" that gives this tubing such a high degree of flexibility. It is this flexibility that makes the cannula so much more comfortable to wear. The referenced Salter patent does not deal with tubing properties at all. The flexible material in that patent refers to the nosepiece.

Claims 6 and 12-compression set less than 45%

Compression set is a standard specification given for flexible materials and is an indication of how a piece of tubing maintains a bent shape after the bending force is removed. One of the biggest problems with cannula tubing is that it has "memory" and takes a long time, if ever, for curls etc. to relax and straighten out. The tubing has to be pulled tight against the face to straighten the tubing and that causes sores. The tubing I use has almost no memory and this is quite important for making a cannula comfortable. The rejection letter points to a line in Salter's patent that teaches a flexible tube but the

patent actually teaches a flexible material for the nasal cannula which I am referring to as a nosepiece. Again, the Salter patent is about the nosepiece and not the tubing. Part of the misunderstanding is the meaning of the word "cannula". The whole thing with tubing, fittings and nosepiece is called a cannula and so is just the nosepiece. In the Salter patent the word cannula refers to the nosepiece only.

Claims 7 and 13 brittle temperature less than -40C

The low brittle temperature of my tubing is a measure of how flexible it is at low temperatures. Regular PVC becomes very stiff in cold temperatures and has been known to break. A cannula that remains flexible in cold weather is a distinct improvement over prior art and is critical to my invention. The Salter patent does not concern tubing properties at all.

Claims 9 and 15 high molecular weight (>100,000)

As before, the Salter patent refers to the material of the nosepiece only.

These all describe the critical properties of the tubing that make it work well in a cannula. These are all outside the specifications of commonly used tubing and also would not be considered to be of use by one skilled in the art. The 10% tensile modulus and compression set are measurements of the flexibility and rubber-like qualities of the tubing. The brittle temperature is a measure of the cold weather flexibility of the preferred tubing. The high molecular weight describes PVC material that can be used to create tubing with the desired properties needed for this invention.

Claims 5 and 11 40-75A hardness

The hardness specification is much lower than the hardness of tubing normally used. Softer generally means more flexible and that is important to my invention but is unsuitable for regular cannulas. The rejection of these claims is based on a patent that teaches flexible tubing with a hardness within the range I am claiming. I have included the reference and drawing

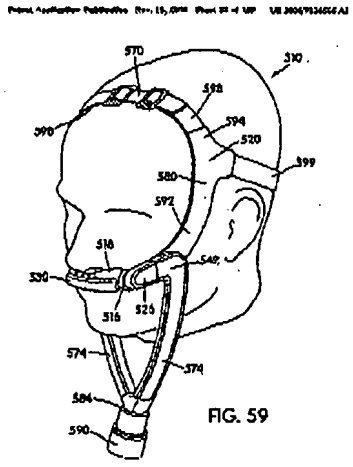


FIG. 59

[0304] The second connector portions 526 may be formed of silicone with a hardness of about 50-60 Shore A hardness. This hardness facilitates assembly, swiveling movement, and seal with the frame 516. However, the second connector portions 526 may be formed of any other suitable material and may have any suitable hardness.

The piece labeled 526 is not a piece of tubing. It is desirable for this part to be fairly rigid so it snaps together and will swivel. Silicone rubber is usually

quite soft. A 50-60 hardness is about as hard as silicone can be so this patent teaches away from mine. Thus it is not reasonable for a skilled person, already aware that soft tubing does not work for cannulas, to look at this non-tubing-like part that is supposed to be hard enough to swivel and from this get the idea to make tubing for a different application with properties directly opposite to both the patent and his own knowledge. My invention uses tubing to support the nosepiece while Gunaratnam has no tubing at all, relying instead on head gear and a rigid support arm. This is exactly what I don't want. If someone were motivated by this patent to put a harness on a Salter cannula, it would lead them father away from my invention.

Obviousness of softer tubing

Even though there is nothing in either the Salter or Gunaratnam patents that would lead someone to consider modifying tubing in a direction that is known not to work it may be possible that some patent out there somewhere may mention soft tubing in conjunction with comfort. But it would not be for use in a cannula. What may seem obvious to an average person in the street is a bad idea to someone skilled in the art and an attempt to build one just by changing tubing would be met with failure. Without the simultaneous knowledge of the nosepiece interaction, the idea or impetus to use soft tubing on a cannula is worthless and would not lead to success. Establishing some reference about soft tubing does not render my invention obvious.

The problems solved by my cannula have been around a long time and a lot of effort has gone into solving these problems as evidenced by the large number of patents. Enough time has passed for obviousness to have surfaced. The idea I came up with does not depend on new technology that I was privy to first nor does it involve some exotic materials that could not be used economically nor is it difficult to build. My idea is a simple solution that is very effective and the fact that no one has done it is proof that it is not obvious.

This invention is not one that someone could sit down, do some calculations and come up with a cannula that works as well as mine. I used tubing with properties that were known to be unsuitable and had to invent a nosepiece to make it work. The idea to use soft tubing is worthless without the right nosepiece and the nosepiece I invented just happened to be right. The result is a cannula that is much more comfortable than anything else available. The flexibility tends to multiply the improvements in many unforeseen ways. For instance the flexible tubing doesn't distort the nosepiece in the package so the nosepiece can be made thinner and lighter. The elastic properties allow the user to pull the nosepiece away from the face to blow one's nose and it snaps back as opposed to having to loosen the tubing enough to pull it away. Because the tubing isn't pulled tight it doesn't need to be thick to prevent flattening. Thus the tubing can be made with thinner walls, reducing both cost and weight. The less everything weighs the easier it is to stay in place. The improvement in comfort is hugely out of proportion to the relatively minor changes that were made.

There is nothing in literature or patents that would lead a person skilled in the arts to any single part of this invention let alone to put together all that was needed to make this invention work. Many people have given much effort and thought over many years attempting to design solutions for just one of the multitude of problems caused by cannulas and my invention solves all of them. As simple as it is, there is no part of my invention that is obvious and the proof is that several generations of inventors have tried to solve problems that still exist.

When determining obviousness one must consider the invention as a whole. My invention involves flexible tubing in combination with a particular nosepiece. A reference that mentions tubing hardness is not sufficient on its own to make a determination of obviousness.

To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. No such line of reasoning was presented.

My idea is simple to understand and simple to implement and will work in more ways than it won't. It is somewhat difficult to show that an idea so simple is not an obvious one. I think the most commanding evidence to support nonobviousness is to point to the long history of the devices, the millions of people who have manufactured, designed, sold and used cannulas and yet no one has put together, or even come close to putting together the pieces to the puzzle. It is not seen in the marketplace or known in the industry and is not seen in cannula patents. The problems my idea solves have been the subject of a wide variety of inventions. (I have included pictures of examples at the end.)

Another powerful argument for nonobviousness is if the idea is an effective solution for a recognized problem. If it is an invention that satisfies a great demand, is successful and far above the rest and there is no hint anywhere than anyone else knows it, that passes the test for an original invention.

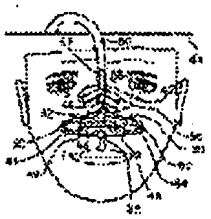
It is everything an invention should be. It is inexpensive, can be mass produced, easy to implement with little change to production methods and equipment, satisfies large demand in growing market and no one else has done anything similar.

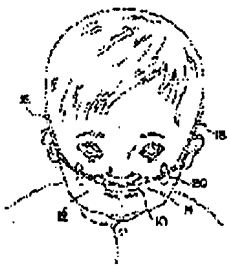
Paul Thompson

Paul Thompson date 7/9/07

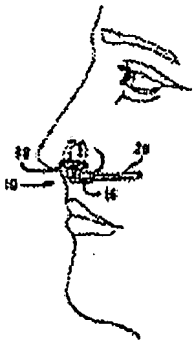
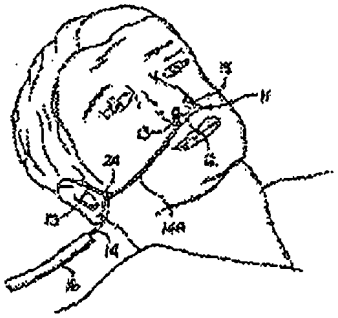
Appendix

These are examples of the many devices that attempt to solve cannula problems

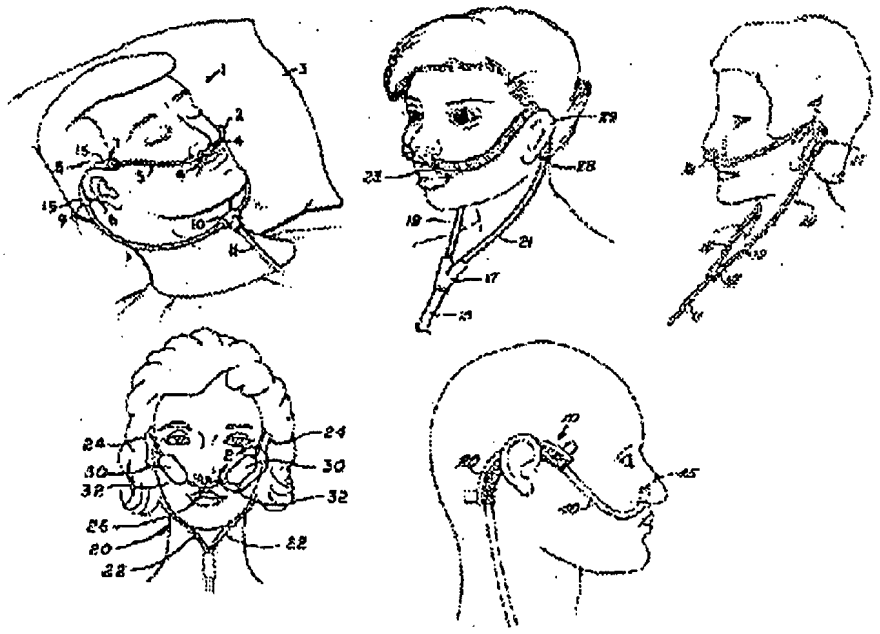



Adhesive devices
These are a few devices that hold the nosepiece in place with adhesive patches or strips. My invention uses a very light nosepiece and silky tubing that drapes right across the face giving it a lot of surface contact to hold it in place. There is no need for adhesive support.

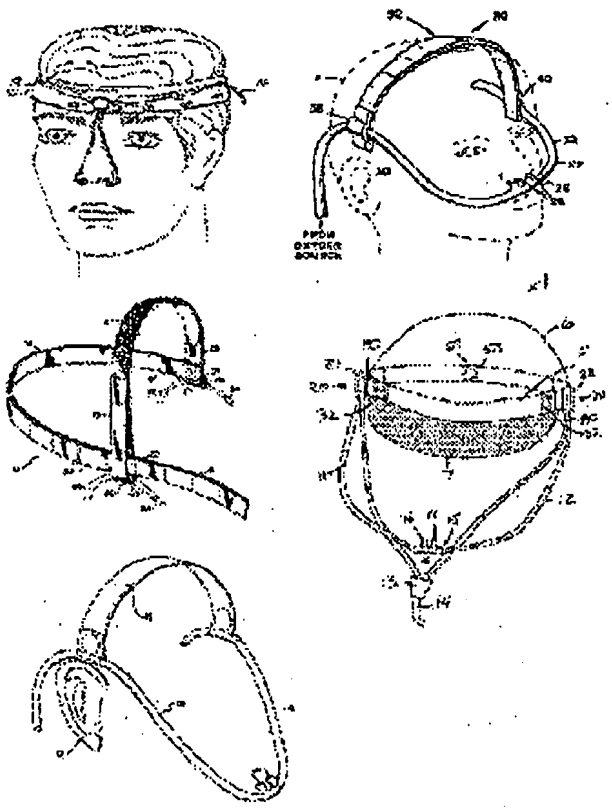



nostril clips
These devices clip onto the bridge between nostrils or wedge themselves into the nostrils to keep them in place. The nosepiece in my invention is shaped like a wide vee and this shape fits the face perfectly. It has no tendency to move out of place because it is in the most natural place it can be. There is no need for any support from the nostrils.



foam cushions

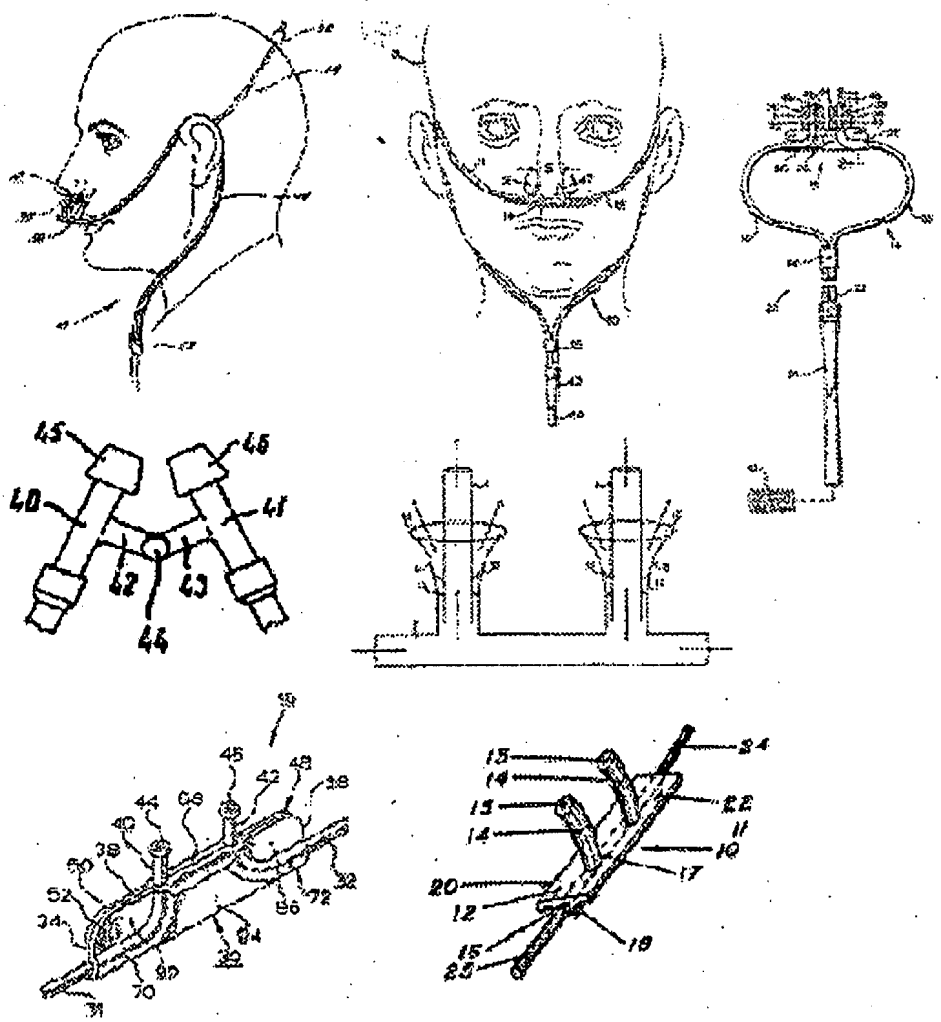
Tight tubing causes sores on the ears and nose and leaves grooves in the cheeks. All these "inventions" use sponge rubber between the tubing and skin. The patent office has determined that a skilled artisan familiar with the use of foam cushions to protect the ears would not have the insight to extend the use of cushions to other areas of irritation. It is not appropriate to make the argument that this same artisan would have the idea to make a cannula with very flexible tubing even though it has never been seen in the marketplace or suggested in a patent and it is common knowledge that this type of tubing does not work for cannulas. In addition to contrary use of the tubing, the artisan must also have the insight to use a certain type of nosepiece to make it work when, again, there is nothing in prior art suggesting such a use.



Head bands

These devices are intended to isolate the bending forces of the tubing from the nosepiece. The tubing between the head band and nosepiece is undisturbed by head movements bcause the head band takes all the force.

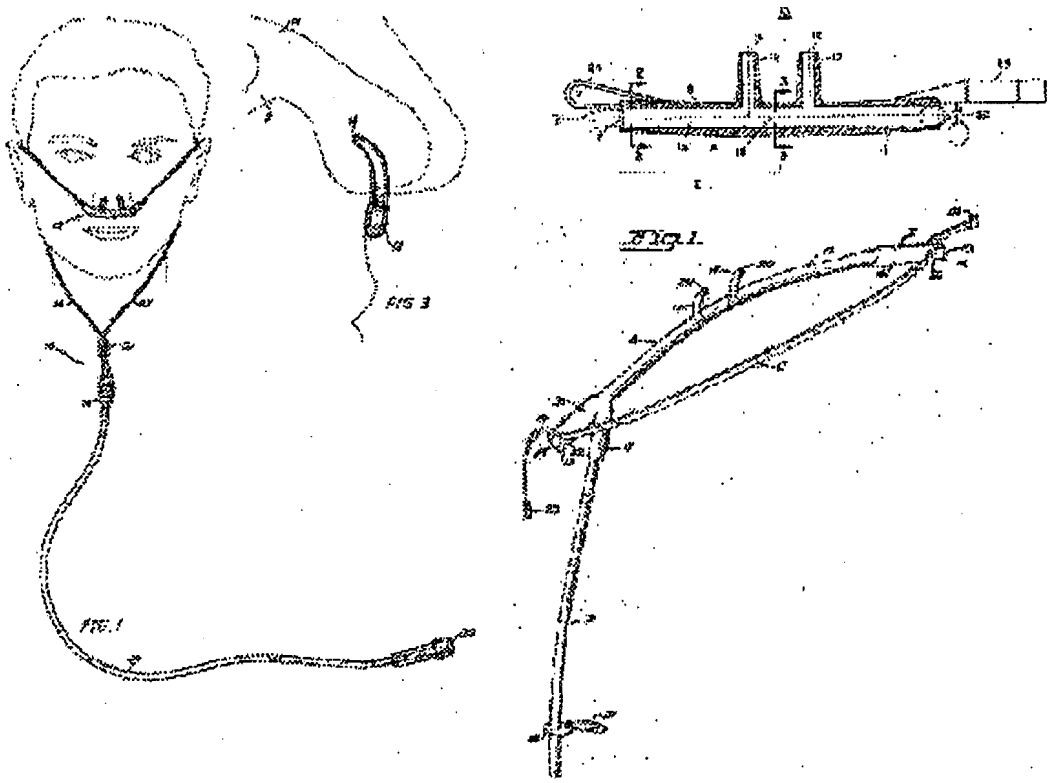
My invention uses such flexible tubing that it readily bends with the head without transmitting force to the face tubing or nosepiece.



nosepiece/prong modifications

Most of these devices are intended to prevent sores inside the nose caused by dry oxygen blowing against sensitive membranes of the nasal walls. This is a problem that still exists with regular cannulas. One uses a flare shape to reduce velocity another has a plate that rests against the lip and forces the prongs to tip in the proper direction. Others are adjustable to fit each user's nose. Sometimes foam is used to center the prong in the nostril. It is important that air is allowed to enter around these devices.

The nosepiece of my invention is shaped like a vee so it stays in the center due to the shape of the face and won't rock from side to side like a straight one. The prongs are angled inward to match the nose shape and the tips are so flexible at the tips they aren't sensed as something in the nose. The secure location of the nosepiece assures proper pointing of oxygen so it doesn't blow on the nasal walls causing sores. This is a major problem with all other cannulas.



bendable bodies

These are included because they are examples of cannula nosepieces that are forced to bend in a direction that keeps the prongs pointed up. The tubing must supply the tension to bend the nosepiece but it doesn't have to keep the prongs pointed properly. Therefore, they should work with very flexible tubing. There are other cannulas on the market that have nosepieces with a low center of gravity that should also work. The Salter cannula, shown in two views at the upper left was a major advance in cannula comfort. It was the first to use a dip-molded nosepiece that is soft and can be made into more shapes than injection molded cannulas. It also has a body that is tall and narrow so it bends in the thin direction. The prongs always point in the right direction relative to the bend so they are less likely to blow against the walls. However, it still happens in some people.

The nosepiece on my cannula fits the shape of the face and stays pointing right without having to bend it. No bending means little tubing tension or pressure on the upper lip.

Paul Thompson 7/9/07